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(54) **Thermally isolated probe**

Thermisch isolierte Sonde

Sonde thermiquement isolée

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(56) References cited:
EP-A- 0 180 368
EP-A- 0 337 724
WO-A-90/05902
US-A- 4 895 164

EP 0 674 162 B1

Description

BACKGROUND OF THE INVENTION

Field of the Invention:

[0001] This invention relates generally to a thermal isolation apparatus for biomedical instrumentation, and more particularly relates to thermally isolating a probe of a biomedical thermometer.

Description of Related Art:

[0002] Medical thermometers are useful in the diagnosis of many diseases. Infrared (IR) biomedical thermometers have been adapted for measuring temperature from the auditory canal and the tympanic membrane. Such thermometers typically have an optical path, for example a waveguide, connecting the tip of the probe to a thermal detector located in the body of the thermometer. Temperature stability of this optical path is desirable so that it does not add unknown thermal components and adversely affect the temperature measurement of the patient. Contact of the probe with the ear of the patient may cause a cooling or heating of the ear canal depending upon the relative temperature of the probe, it may also cause heat of the patient to be conducted through the probe and to the waveguide which may result in "hot spots" or temperature variations in the waveguide, and an inaccurate temperature measurement of the patient may result. While it is desirable that physical contact of the probe with the patient not occur, such contact is inevitable. The length of such contact and the point or points of the probe contacting the patient vary with each user of the probe and with the physical configuration of each patient. While probe covers may be used over the thermometer probe to prevent contamination of the probe, these covers typically do not provide substantial thermal isolation by themselves and in fact may, if the probe cover is substantially hotter or colder than the probe or the ear canal, themselves undesirably affect the thermal performance of the probe and the temperature of the ear canal.

[0003] EPA 337 724 A2 discloses an infrared sensing temperature probe which exhibits these problems. In order to maintain accuracy, the probe described there endeavors to maintain the infrared sensing path at thermal equilibrium. Accordingly, the pieces of that path, including a hard cap, an optical guide, and the infrared sensor, are thermally connected together in a thermal conduction path. The probe cover comes near to the hard cap; and thus, hotter or cooler probe covers must affect, at least transiently, the temperature of parts, such as the hard cap, which the system endeavors to hold in thermal equilibrium. Moreover, if damage or contamination occurs to the hard cap of the probe described there, the entire mechanism apparently must be replaced, since the cap is not separately replaceable.

[0004] It would be desirable for an infrared biomedical probe to include an apparatus for thermally isolating the optical path of the probe from thermal energy which may be transferred to or from the probe by patient contact, by installing a new probe cover, and from other sources of heat or cold whth which the probe may come into contact during use. It would further be desirable to be able to readily replace critical items protecting the internal mechanism of the probe, such as the hard cap of EPA 337 724 A2. The present invention addresses this need.

SUMMARY OF THE INVENTION

[0005] Briefly, and in general terms, the present invention provides a probe having replaceable elements to communicate infrared energy from a patient to a detector. The probe has an opening at the patient end for infrared energy to enter, and an energy conducting path to convey the infrared energy from the opening to a sensor. Disposed in the path is a window which is transparent to the infrared energy. The window is formed of a rigid material, and forms part of an assembly which is readily removeable and replaceable.

[0006] The probe also includes an outer boot which is positioned over the energy conducting path and the replaceable window. The outer boot is so mounted that it must first be removed before the replaceable window assembly can be removed and replaced.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007]

FIG. 1 is a front perspective view of a hand held biomedical thermometer which shows the protruding probe;
FIG. 2 is a partial sectional view through the axis of the probe of the thermometer shown in FIG. 1; and
FIG. 3 is an exploded view of the thermal isolation boot and the heat sink containing the waveguide portion of the probe of FIG. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0008] As is shown in the exemplary drawings, the invention is embodied in a thermal isolation apparatus for a probe of a biomedical thermometer. The probe includes a waveguide which receives and channels infrared radiation to an infrared detector in the body of the thermometer. The thermal isolation apparatus isolates the waveguide and other optical path components from producing or receiving extraneous thermal influences which may arise during use.

[0009] Referring now to FIGS. 1 and 2, a biomedical infrared thermometer 10 is shown for sensing the temperature of a patient. The body of the biomedical thermometer 11 houses an infrared radiation detector (not

shown) and functional elements necessary for the detection of the temperature of the patient based upon the infrared radiation received by the thermometer from a body cavity such as the tympanic canal, or other portions of the patient's anatomy. The thermometer is preferably a hand held type including a handle 12, and an on-off trigger switch 14, so that the temperature readings may be quickly taken by the user by pointing the protruding probe 16 end at the target area of the patient from which a temperature reading is to be taken, such as the tympanic membrane.

[0010] The probe 16 includes a waveguide portion 18, which is preferably formed of a highly thermally conductive material such as copper, although it may be formed of other good heat conductive and reflective or platable material such as aluminum, brass, stainless steel, or the like. Surrounding the waveguide 18 is a heat sink 20. The heat sink may be integral with the waveguide 18 or may be a supporting structure within which the waveguide is mounted. Preferably, the waveguide is formed by forming a channel through the heat sink and plating the channel with a substance which is highly reflective to infrared energy, such as gold. In another embodiment, the waveguide may be formed by inserting an intimately bonded sleeve of reflective material into the channel. The heat sink is in thermal communication with a heat sink 19 in the body 11 of the thermometer formed of a similar material. In the embodiment shown in FIG. 2, the waveguide is generally cylindrical in shape and extends axially through the heat sink 20 for communication of infrared energy from the temperature source to the infrared detector.

[0011] In another embodiment, the waveguide is frustro-conically shaped with the larger opening at the distal end of the probe for directed at the patient. The smaller opening was located facing to the IR detector in the body of the thermometer. This configuration resulted in more IR energy from the patient reaching the detector. In this embodiment, the waveguide opening at the distal end of the probe was selected to be a particular size based on the opening of the average ear. This size was larger than the size of the waveguide opening permitted by the particular detector used. Thus a frustro-conically shaped waveguide was used, although with other applications, a differently shaped waveguide may be more appropriate.

[0012] Referring now to FIGS. 2 and 3, a window 22 is disposed at the end of the waveguide 18, and is mounted and protected in a transparent sleeve 23 placed over the distal tip of the waveguide 18 and the window 22. The window 22 may be formed of a glass-like material such as zinc selenide which is substantially transparent to infrared energy. Alternatively, the window could be made of polyethylene or other similar materials that are also substantially transparent to infrared energy. In the embodiment disclosed, the zinc selenide window passes the infrared energy while sealing the end of the waveguide from contamination.

[0013] The sleeve 23 is preferably generally tubular and is made of a rugged material such as stainless steel to protect the window 22 and waveguide end. Additionally, the material is chosen to have a low thermal conductivity to provide additional insulation for these same two elements. In one embodiment, low thermal conductivity stainless steel was used. The sleeve 23 may also include a flange 32 at one end to fit snugly against a correspondingly inset portion of the heat sink 20. The sleeve 23 preferably includes a lip (not shown) around the inside of the end of the sleeve away from the flange end 25 for retention of the window 22 during assembly, and a series of holes (not shown) around the lip end of the sleeve through which adhesive may be applied to the edge of the window to permanently bond it in place in the sleeve 23. The window 22 and the sleeve 23 assembly can therefore be readily removed and replaced by sliding the sleeve 23 off the end of the waveguide 18.

[0014] The heat sink 20 shown in FIGS. 2 and 3, is generally conically shaped so that it will fit inside the outer boot 24 as is discussed below. The heat sink 20 is used to insulate the waveguide 18 from extraneous heat sources and to avoid the generation of "hot spots" or temperature variations along the waveguide. As used herein, hot spots are areas of significantly different temperature from the average temperature of the waveguide. When the probe is used to measure the temperature of a patient, it may come into contact with the patient at a point or points on the probe. It is desirable that the heat of the patient received by the probe due to contact at this point or points, not be conducted to the waveguide or if it is, at least be conducted evenly around the waveguide so that hot spots are not formed. In order to resist the formation of hot spots, the heat sink 20 is formed of a material having high thermal conductivity and diffusivity. By using such a material, the heat conducted to the heat sink at this point or points will be evenly distributed throughout the heat sink and along the waveguide. Additionally, the mass of the heat sink 20 is selected to have a high heat capacity. Depending on its size, the heat sink may present such a large heat capacity to the heat or cold source, that before any temperature change can reach the waveguide, which is located at the center of the heat sink, the temperature measurement of the patient will have been completed. In the embodiment shown in the FIGS., the heat sink 20 was formed of copper. In addition to having high thermal conductivity, high thermal diffusivity and sufficient mass for high heat capacity, it provides an excellent surface on which to plate highly thermally conductive materials, such as gold, to form the waveguide 18.

[0015] Another means of thermally isolating the probe includes forming a closed air space around the optical path. Mounted over the heat sink 20 of the probe is an outer boot 24 which contacts the heat sink 20 at the proximal base portion 26 of the boot, and contacts the sleeve 23 at the distal tip portion 28 of the boot. The outer boot may be approximately 2.54 mm (0.10 inch)

thick and is preferably formed of a durable, hard plastic such as ABS, which is well known for its durability and thermal insulation properties and which can be plated with reflective materials. However, other materials may also be suitable. One or more tabs 27 are preferably provided for interfacing with corresponding slots (not shown) in the body 11 of the thermometer for securing the boot 24 to the thermometer. The inner surface of the boot between the proximal and distal areas of contact with the waveguide 18 is preferably spaced from the outer surface of the waveguide 18 by typically approximately 1.02 tmm (0.04 inches) although the spacing can vary, depending on the amount of air desired. A chamber forming a closed air space or air gap 25 is thereby formed between the boot and the waveguide, providing a layer of insulative air around the probe to further protect the waveguide channel from transient temperature changes due to patient contact or other extraneous thermal sources and protecting the. target from temperature change due to contact with the probe.

[0016] The air gap preferably extends inside the boot 24 from the area where the proximal base portion 26 of the boot contacts the heat sink 20 to an area approximately where the distal tip portion 28 of the boot contacts the sleeve 23 over the distal tip of the probe. The distal tip 28 of the boot is preferably involuted to form an inwardly folded extension 29 which slips over the sleeve 23. This configuration holds the window and sleeve in position at the distal end of the waveguide 18. The air gap therefore extends forwardly between this inwardly folded extension 29 and the base portion 26 of the boot so that the air gap thermally isolates the entire length of the waveguide in the probe from thermal influences outside the boot.

[0017] In considering the amount of thermal isolation required for the probe, at least three situations would typically be considered: 1) the patient could be hot relative to the temperature of the probe; 2) the patient could be cold relative to the temperature of the probe; and 3) the protective probe cover placed over the probe for hygienic and protective reasons could be either hot or cold relative to the probe temperature.

[0018] In addition to the above three situations, two other factors are normally considered when determining the dimension of the air gap: 1) the amount of time the detector takes to complete its temperature measurement; and 2) the typical amount of time that the instrument operator will leave the probe in contact with the patient while taking the patient's temperature.

[0019] In an embodiment of the invention, an air gap formed between the heat sink 20 and the inside surface of the outer boot 24 within the range 0.51 to 1.52 mm (0.020 to 0.060 in.) was found to be very effective in isolating the optical path in the probe from external temperature influences encountered in normal use. Thus the combination of a heat sink with high thermal diffusivity, high thermal conductivity, sufficient thermal mass for high heat capacity and a closed air space having low thermal diffusivity and conductivity results in relative thermal isolation. The heat sink and air gap thermally isolate the infrared optical path in the probe portion of the thermometer from extraneous thermal changes. Additionally, the combination of the two provide enough thermal protection such that a measurement may be completed prior to thermal influences reaching the waveguide.

Claims

1. A probe (16) having replaceable elements adapted to communicate electromagnetic energy in the form of infrared radiation from a patient to an energy detector, the probe (16) comprising a distal opening through which energy from the patient enters the probe and an energy conducting path to the energy detector, **characterized in that** the probe (16) includes;

    a replaceable window (22) formed of a rigid material transparent to said electromagnetic energy, the window (22) being mounted in the energy conducting path of the probe as part of an assembly (22, 23) configured to removably position the window (22) such that the assembly (22, 23) is readily removed and replaced; and
    an outer boot (24) removably positioned over the energy conducting path and the replaceable window (22) and mounted such that the outer boot (24) must be removed before the replaceable window can be removed and replaced.

2. The probe according to claim 1, further **characterized in that** the outer removable boot (24) is configured to secure the window (22) at a position internal to the boot (24) and to firmly retain the window (22) at a position in the energy path such that the window (22) is not removable until after the boot (24) has been removed.

3. The probe according to claim 1 or claim 2, further **characterized in that:**

    the replaceable window (22) is mounted in an assembly (22, 23) which includes a replaceable sleeve (23) having an opening within which the window (22) is mounted into position; and
    the removable boot contacts the sleeve (23) and retains the sleeve (23) and the window (22) at positions in the energy conducting path wherein the sleeve (23) and the window (22) may be removed from the energy conducting path and replaced after the boot (24) has been removed.

4. The probe according to claim 3, further **characterized in that:**

the sleeve (23) comprises a mounting flange (25);
the energy conducting path comprises a mounting surface on which the sleeve is slidably mounted; and the outer boot comprises a window retainer wherein the window retainer of the outer boot contacts the flange (25) of the sleeve (23) to secure the sleeve (23) on the mounting surface such that the window (22) is positioned at the position in the energy path when the boot (24) is in place, and the sleeve (23) and window (22) are slidably removable from the energy conducting path and can be replaced when the boot (24) is removed from the probe (16).

5. The probe according to claim 3, further **characterized in that** the mounting surface of the energy conducting path comprises an inset portion for receiving the flange (25) of the sleeve (23).

6. The probe (16) according to any of claims 1 through 5, further **characterized in that:**

the removable outer boot (24) is formed of a durable material; and
the removable outer boot extends distally beyond the replaceable window (22) to provide shock protection to the window.

7. The probe according to claims 1 through 5, further **characterized in that:**

the removable outer boot (24) is formed of a durable material and comprises a distal involution; and
the involution of the removable outer boot (24) extends distally beyond the window (22) to provide shock protection to the window (22).

Patentansprüche

1. Sonde (16) mit austauschbaren Elementen, die sich zur Übertragung elektromagnetischer Energie in Form von Infrarotstrahlung von einem Patienten zu einem Energiedetektor eignet, wobei die Sonde (16) eine distale Öffnung aufweist, durch die Energie von dem Patienten in die Sonde eintritt, und mit einem Energieleitpfad zu dem Energiedetektor, **dadurch gekennzeichnet, dass** die Sonde (16) folgendes aufweist:

ein austauschbares Fenster (22), das aus einem steifen Material gebildet wird, das für die genannte elektromagnetische Energie durchlässig ist, wobei das Fenster (22) in dem Energieleitpfad der Sonde als Teil eines Zusammenbaus (22, 23) angebracht ist, der so konfiguriert ist, dass das Fenster (22) entfernbar positioniert wird, so dass der Zusammenbau (22, 23) einfach entfernt und ausgetauscht werden kann; und
eine äußere Manschette (24), die entfernbar über dem Energieleitpfad und dem austauschbaren Fenster (22) positioniert und derart angebracht ist, dass die äußere Manschette (24) entfernt werden muss, bevor das austauschbare Fenster entfernt und ausgetauscht werden kann.

2. Sonde nach Anspruch 1, ferner **dadurch gekennzeichnet, dass** die äußere entfernbare Manschette (24) so konfiguriert ist, dass sie das Fenster (22) an einer Position innerhalb der Manschette (24) sichert und das Fenster (22) fest an einer Position in dem Energiepfad hält, so dass das Fenster (22) nicht entfernt werden kann, solange die Manschette (24) nicht entfernt worden ist.

3. Sonde nach Anspruch 1 oder 2, ferner **dadurch gekennzeichnet, dass:**

das austauschbare Fenster (22) in einem Zusammenbau (22, 23) angebracht ist, der eine austauschbare Hülle (23) mit einer Öffnung aufweist, in der das Fenster (22) an der Verwendungsposition angebracht ist; und
die entfernbare Manschette die Hülle (23) berührt und die Hülle (23) und das Fenster (22) an Positionen in dem Energieleitpfad hält, wobei die Hülle (23) und das Fenster (22) aus dem Energieleitpfad entfernt und ausgetauscht werden können, nachdem die Manschette (24) entfernt worden ist.

4. Sonde nach Anspruch 3, ferner **dadurch gekennzeichnet, dass:**

die Hülle (23) einen Befestigungsflansch (25) umfasst;
der Energieleitpfad eine Befestigungsoberfläche umfasst, an der die Hülle verschiebbar angebracht ist; und wobei die äußere Manschette eine Fensterhalteeinrichtung umfasst, wobei die Fensterhalteeinrichtung der äußeren Manschette den Flansch (25) der Hülle (23) berührt, so dass die Hülle (23) an der Befestigungsoberfläche befestigt wird, so dass das Fenster (22) an der Position in dem Energiepfad positioniert wird, wenn sich die Manschette (24) an der Verwendungsposition befindet, und wobei die Hülle (23) und das Fenster (22) verschiebbar aus

dem Energieleitpfad entfernt und ausgetauscht werden können, wenn die Manschette (24) von der Sonde (16) entfernt worden ist.

5. Sonde nach Anspruch 3, ferner **dadurch gekennzeichnet, dass** die Befestigungsoberfläche des Energieleitpfads einen Einsatzabschnitt zur Aufnahme des Flanschs (25) der Hülle (23) umfasst.

6. Sonde (16) nach einem der Ansprüche 1 bis 5, ferner **dadurch gekennzeichnet, dass:**

   die entfernbare äußere Manschette (24) aus einem haltbaren Material hergestellt wird; und dass
   sich die entfernbare äußere Manschette distal über das austauschbare Fenster hinaus erstreckt, um für das Fenster einen Stoßschutz vorzusehen.

7. Sonde nach einem der Ansprüche 1 bis 5, ferner **dadurch gekennzeichnet, dass:**

   die entfernbare äußere Manschette (24) aus einem haltbaren Material hergestellt wird und eine distale Involution aufweist; und dass
   sich die Involution der entfernbaren äußeren Manschette (24) distal über das Fenster (22) hinaus erstreckt, um einem Stoßschutz für das Fenster (22) vorzusehen.

Revendications

1. Sonde (16) ayant des éléments remplaçables adaptés pour communiquer de l'énergie électromagnétique sous forme de radiation infrarouge depuis un patient vers un détecteur d'énergie, la sonde (16) comprenant une ouverture distale à travers laquelle l'énergie issue du patient entre dans la sonde et un chemin de conduction d'énergie vers le détecteur d'énergie, **caractérisée en ce que** la sonde (16) comprend :

   une fenêtre remplaçable (22) formée en un matériau rigide transparent pour ladite énergie électromagnétique, la fenêtre (22) étant montée dans le chemin de conduction d'énergie de la sonde en tant que partie d'un ensemble (22, 23) configuré pour positionner la fenêtre (22) de manière amovible de telle sorte que l'ensemble (22, 23) est facilement retiré et remplacé ; et
   un embout externe (24) positionné de manière amovible par-dessus le chemin de conduction d'énergie et la fenêtre remplaçable (22) et monté de telle manière que l'embout externe (24) doit être retiré avant que la fenêtre remplaçable ne puisse être retirée et remplacée.

2. Sonde selon la revendication 1, **caractérisée en outre en ce que** l'embout externe amovible (24) est configuré pour fixer la fenêtre (22) en position interne par rapport à l'embout (24) et pour retenir fermement la fenêtre (22) dans une position dans le chemin d'énergie de telle sorte que la fenêtre (22) n'est pas amovible tant que l'embout (24) n'a pas été retiré.

3. Sonde selon la revendication 1 ou 2, **caractérisée en outre en ce que** :

   la fenêtre remplaçable (22) est montée dans un ensemble (22, 23) incluant un manchon remplaçable (23) ayant une ouverture à l'intérieur de laquelle la fenêtre (22) est positionnée ; et
   l'embout amovible est en contact avec le manchon (23) et retient le manchon (23) et la fenêtre (22) en position dans le chemin de conduction d'énergie, dans laquelle le manchon (23) et la fenêtre (22) peuvent être retirés du chemin de conduction d'énergie et remplacés après que l'embout (24) a été retiré.

4. Sonde selon la revendication 3, **caractérisée en outre en ce que** :

   le manchon (23) comprend une collerette de montage (25) ;
   le chemin de conduction d'énergie comprend une surface de montage sur laquelle le manchon est monté de manière coulissante ; et
   l'embout externe comprend un dispositif de retenue de la fenêtre, dans laquelle le dispositif de retenue de la fenêtre de l'embout externe est en contact avec la collerette (25) du manchon (23) pour fixer le manchon (23) sur la surface de montage de telle manière que la fenêtre (22) est maintenue en position dans le chemin d'énergie lorsque l'embout (24) est en place, et le manchon (23) et la fenêtre (22) peuvent être retirés de manière coulissante du chemin de conduction d'énergie et peuvent être remplacés lorsque l'embout (24) est retiré de la sonde (16).

5. Sonde selon la revendication 3, **caractérisée en outre en ce que** la surface de montage du chemin de conduction d'énergie comprend une partie encastrée pour recevoir la collerette (25) du manchon (23).

6. Sonde (16) selon l'une quelconque des revendications 1 à 5, **caractérisée en outre en ce que** :

   l'embout externe amovible (24) est formé en un

matériau durable ; et
l'embout externe amovible s'étend distalement au-delà de la fenêtre remplaçable (22) pour offrir une protection contre les chocs à la fenêtre.

7. Sonde selon les revendications 1 à 5, **caractérisée en outre en ce que :**

l'embout externe amovible (24) est formé en un matériau durable et comprend une involution distale ; et
l'involution de l'embout externe amovible (24) s'étend distalement au-delà de la fenêtre (22) pour offrir une protection contre les chocs à la fenêtre (22).

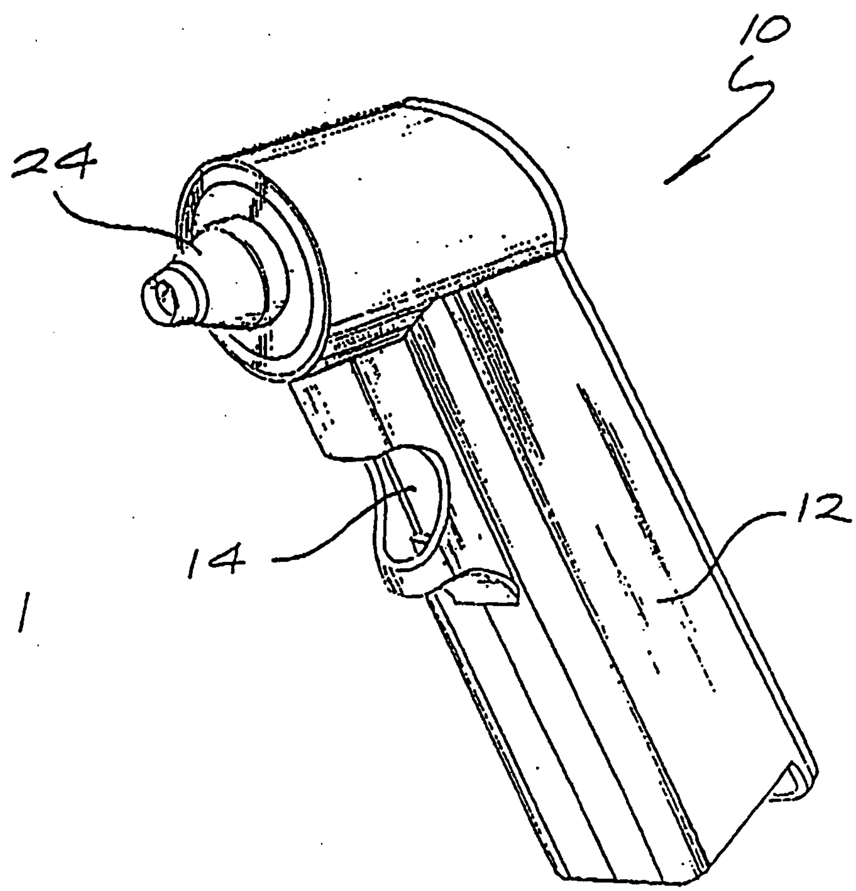

FIG. 1

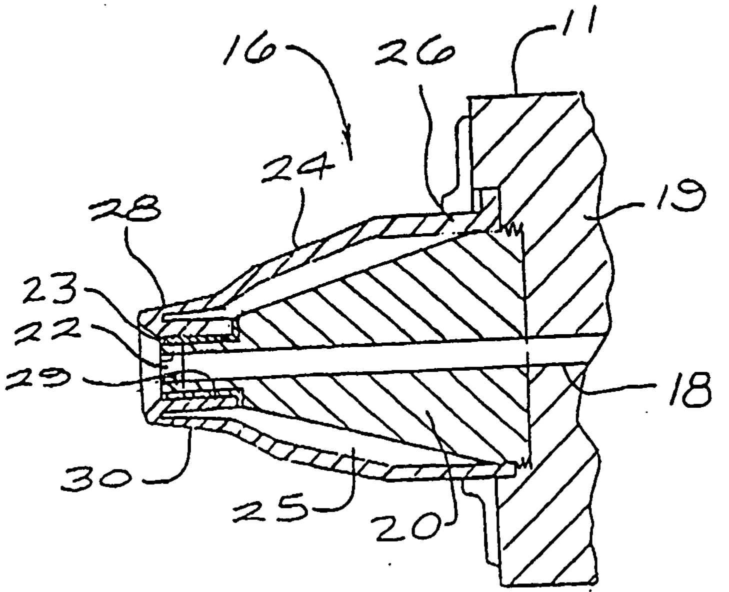

FIG. 2

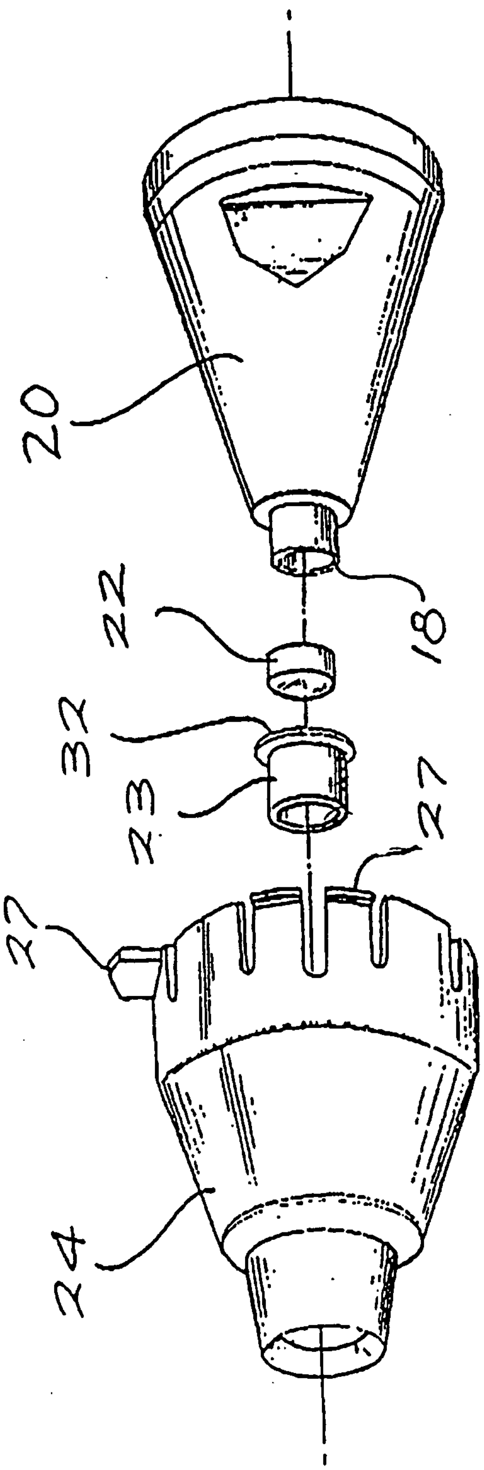

FIG. 3